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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,003	10/30/2003	Itzhak Bentwich		1002

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/707,003	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11, 12 drawn to a bioinformatically detectable viral gene and a vector comprising the gene, probes, etc. classified in class 702, subclass 20. If this group is elected, further restriction, and further election of species is set forth below.

II. Claims 9, 10, drawn to a method of inhibiting translation using a vector, classified in at least class 514, subclass 44. If this group is elected, further restriction, and further election of species is set forth below.

III. Claim 13, drawn to a method of detecting expression using a probe, classified in class 435, subclass 6. If this group is elected, further restriction, and further election of species is set forth below.

IV. Claim 14, drawn to a composition comprising a probe and "a gene expression detector", classified in at least class 536, subclass 23.1. If this group is elected, further restriction, and further election of species is set forth below.

V. Claims 15, drawn to an unspecified uncharacterized antiviral substance "capable of neutralizing RNA, classified in at least class 514, subclass 2+. If this group is elected, further restriction, and further election of species is set forth below.

VI. Claim 16, drawn to an antiviral substance which is RNA, classified in class 514, subclass 44. If this group is elected, further restriction, and further election of species is set forth below.

VII. Claim 17, drawn to an antiviral substance which "comprises immunologically neutralizing", classified in at least class 424, subclass 184.1. If this group is elected, further restriction, and further election of species is set forth below.

VIII. Claims 18-19, drawn to methods of anti-viral treatment by neutralizing RNA, classified in class 514, subclass 44. If this group is elected, further restriction, and further election of species is set forth below.

IX. Claim 20, drawn to methods of anti-viral treatment by "immunologically neutralizing", classified in class 424, subclass 184.1. If this group is elected, further restriction, and further election of species is set forth below.

FURTHER RESTRICTION FOR EACH GROUP CITED ABOVE

In addition, each Group detailed above reads on patentably distinct SEQ ID Numbers. Each Group requires a viral gene which encodes an RNA. Applicant is required to elect a single viral gene which encodes an RNA. The genes are detailed in the specification and sequence listing. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO. (See MPEP 803.04). Applicant must specifically identify the SEQ ID NO: and gene name, if available, for the sequence elected. For Groups drawn to methods of use or methods of treatment, the same election is required. For Group V, the antiviral substance must be specified: by SEQ ID NO: if is it a nucleic acid, or by other designation if not.

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products have multiple distinct uses such as in methods of detection by hybridization, methods of recombinantly expressing polypeptides, methods of treatment, etc.

Inventions I and IV are independent and distinct as they are drawn to differing compositions of matter. The composition of Invention IV comprises detection means not required or recited in invention I.

Inventions I and V are independent and distinct as they are drawn to differing compositions of matter. Invention V is drawn to an unspecified, uncharacterized antiviral substance, which can include chemicals, proteins, small molecules or nucleic acids.

Inventions I and VI-IX are independent and distinct as the product of Invention I is not used or required for the practice of Inventions VI-IX.

Inventions II and III are independent and distinct, as they are drawn to differing methods having differing steps and differing goals.

Inventions II and IV-IX are independent and distinct, as the method of Invention II does not use or require the subjects of inventions IV-IX.

Inventions III and IV-IX are independent and distinct, as the method of Invention II does not use or require the subjects of inventions IV-IX.

Invention IV is independent and distinct from each other group, as it is not used or required for any other recited group.

Inventions V-VII are each independent and distinct as they are drawn to differing compositions of matter. Invention V is drawn to an uncharacterized, unspecified anti-viral substance. Invention VI is drawn to an antiviral substance which is RNA. Invention VII is drawn to an immunologically neutralizing composition which apparently comprises antibodies. Each of these compositions is structurally and functionally distinct, require search in differing areas.

Inventions V-VII and VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each composition has multiple uses other than in anti-viral treatment. Antibodies can be used to isolate proteins, or in methods of diagnosis. Nucleic acids can be used in hybridization methods, PCR methods, or recombinant expression. Small molecules, drugs or other compounds falling within Group V can be used as molecular weights or standards.

Each of the above listed groups requires significantly differing search strategies in differing areas of patent, and non-patent literature. The search of all the listed inventions would pose an undue burden upon the examiner if not restricted.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species for All Groups

Claims 1-20 are generic to a plurality of disclosed patentably distinct species comprising an unspecified host target gene. For the purposes of initial examination Applicant is required to elect a single host target gene. This elected host target gene MUST be an appropriate target for

the viral gene encoding an RNA elected above. Each of the target genes is distinct as each has differing sequences and functions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered** as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined**. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Conclusion

A fully responsive reply will comprise the election of a group, the election of a viral gene encoding an RNA, and the election of a target host gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of

document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

MARY K. ZEMAN
PRIMARY EXAMINER
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2/6/06